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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Leonard et al. December 18, 2001

Predecessor Serial No.: 09/391,796 Predecessor Group Art Unit No.: 1615

Predecessor Filing Date: September 9, 1999 Predecessor Examiner: B. Seidleck

For: PAROXETINE CONTROLLED RELEASE COMPOSTIONS

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

This application is a continuation of Application Serial No. 09/391,796, filed September 9, 1999. Prior to examination of this application, Applicants request entry of the following amendments and remarks into the record.

Please amend the application as follows.

Please cancel claims 1 to 8 and add claims 9 to 24 as follows.

9. An oral pharmaceutical formulation comprising a selective serotonin reuptake inhibitor (SSRI) wherein the improvement comprises, reducing the incidence of nausea and vomiting associated with the administration of the SSRI consisting essentially of a controlled release or delayed release formulation of an SSRI.

10. An oral controlled release or delayed release pharmaceutical formulation of paroxetine, fluoxetine, fluroxamine or sertraline, or a pharmaceutically acceptable salt thereof.

11. The formulation of claim 10 wherein the compound is paroxetine or a pharmaceutically acceptable salt thereof.

12. The formulation of claim 9 which comprises enteric coated tablets or caplets, wax or polymer coated tablet or caplets or time-release matrices, or combinations thereof.

13. The formulation of claim 10 which comprises enteric coated tablets or caplets, wax or polymer coated tablet or caplets or time-release matrices, or combinations thereof.

14. The formulation of claim 9 which is a polymeric controlled release composition comprising a reaction complex formed by the interaction of (1) a calcium polycarbophil component which is a water-swellable, but water insoluble, fibrous cross-linked carboxy-functional polymer, said polymer containing (a) a plurality of repeating units of which at least about 80% contain at least one carboxyl functionality, and (b) about 0.05 to about 1.5% cross-linking agent substantially free from polyalkenyl polyether, said percentages being based upon the weights of unpolymerized repeating unit and cross-linking agent, respectively with (2) water, in the presence of an SSRI.

15. The formulation of claim 10 which is a polymeric controlled release composition comprising a reaction complex formed by the interaction of (1) a calcium polycarbophil component which is a water-swellable, but water insoluble, fibrous cross-linked carboxy-functional polymer, said polymer containing (a) a plurality of repeating units of which at least about 80% contain at least one carboxyl functionality, and (b) about 0.05 to about 1.5% cross-linking agent substantially free from polyalkenyl polyether, said percentages being based upon the weights of unpolymerized repeating unit and cross-linking agent, respectively with (2) water, in the presence of paroxetine, fluoxetine, fluroxamine or sertraline, or a pharmaceutically acceptable salt thereof.

16. The formulation of claim 15 in which the SSRI is paroxetine or a pharmaceutically acceptable salt thereof.

17. The formulation of claim 9, which is a system for the controlled release of an active substance which is an SSRI, comprising (a) a deposit-core comprising an effective amount of the active substance and having defined geometric form, and (b) a support-platform applied to said deposit-core, wherein said deposit-core contains at least the active substance, and at least one member selected from the group consisting of (1) a polymeric material which swells on contact with water or aqueous liquids and a gellable

polymeric material wherein the ratio of the said swellable polymeric material to said gellable polymeric materials in the range 1:9 to 9:1, and (2) a single polymeric material having both swelling and gelling properties, and wherein the support-platform is an elastic support, applied to said deposit-core so that it partially covers the surface of the deposit-core and follows changes due to hydration of the deposit-core and is slowly soluble and/or slowly gellable in aqueous fluids.

18. The formulation of claim 10, which is a system for the controlled release of paroxetine, fluoxetine, fluroxamine or sertraline, or a pharmaceutically acceptable salt thereof, comprising (a) a deposit-core comprising an effective amount of the active substance and having defined geometric form, and (b) a support-platform applied to said deposit-core, wherein said deposit-core contains at least the active substance, and at least one member selected from the group consisting of (1) a polymeric material which swells on contact with water or aqueous liquids and a gellable polymeric material wherein the ratio of the said swellable polymeric material to said gellable polymeric materials in the range 1:9 to 9:1, and (2) a single polymeric material having both swelling and gelling properties, and wherein the support-platform is an elastic support, applied to said deposit-core so that it partially covers the surface of the deposit-core and follows changes due to hydration of the deposit-core and is slowly soluble and/or slowly gellable in aqueous fluids.

19. The formulation of claim 18 in which the SSRI is paroxetine or a pharmaceutically acceptable salt thereof.

20. A method of treating or preventing one or more of the disorders which comprises administering an effective and/or a prophylactic amount of a controlled release or delayed release formulation of claim 9 to a sufferer in need thereof.

21. A method of treating or preventing one or more of the disorders which comprises administering an effective and/or a prophylactic amount of a controlled release or delayed release formulation of claim 10 to a sufferer in need thereof.

22. A process for preparing a controlled or delayed release formulation of an SSRI which comprises combining (1) a calcium polycarbophil component which is a water-swellable, but water insoluble, fibrous cross-linked carboxy-functional polymer, said polymer containing (a) a plurality of repeating units of which at least about 80%

contain at least one carboxyl functionality, and (b) about 0.05 to about 1.5% cross-linking agent substantially free from polyalkenyl polyether, said percentages being based upon the weights of unpolymerised repeating unit and cross-linking agent, respectively, with (2) water, in the presence of an SSRI.

23. The process of claim 22 in which the SSRI is paroxetine, fluoxetine, fluroxamine or sertraline, or a pharmaceutically acceptable salt thereof.

24. The process of claim 23 in which the SSRI is paroxetine or a pharmaceutically acceptable salt thereof.

REMARKS

Applicants respectfully request examination of the instant application as amended herein. The instant amendments are made to eliminate multiple dependent claims and put the application in better form for examination.

If any matters remain to be resolved before search, examination and allowance, or discussion of any matter will facilitate the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number provided.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Applicants note that all of the previously pending claims have been deleted and replaced by a new claim set. As such, a marked-up version of the claims is not necessary.